REMARKS

Claims 4, 41 and 44 have been amended.

Claim 43 has been canceled.

Claim 45 has been added.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-15

Applicants respectfully traverse the rejection of these claims.

Claim 1 claims "[a] system for preparing a graft vessel for anastomosis, comprising: a functional package comprising a tray in which at least one recess is defined; and an assembly held in at least one said recess, said assembly comprising a crown and an anastomosis device connected to said crown; wherein at least one said recess is configured to hold a biocompatible fluid."

In contrast, U.S. Pat. No. 5,695,504 to Gifford ("Gifford") does not expressly or inherently describe each and every element of claim 1. The Office Action states that "Gifford discloses a system for preparing a graft vessel comprising a functional package comprising a tray with at least one recess (Column 69 lines 45-62)...wherein at least one recess is configured to hold a biocompatible fluid (Column 69 lines 45-62)." That cited text states:

> Any one of the one or two-piece embodiments of the anastomosis staple device can be supplied preattached to a prosthetic graft vessel. For instance, the two-piece anastomosis staple device could be supplied in a kit, including a natural or artificial graft that is prepared with a coupling member

> attached to one or both ends and one or two anchor members for attachment to the target vessel(s). Likewise, the one-piece anastomosis staple device can be supplied in a procedural kit preattached to a prosthetic graft vessel. This is equally applicable to artificial graft materials, such as PTFE or Dacron grafts, or to natural biological graft materials; including allografts of human graft vessels, or xenografts such as bovine or porcine graft vessels, either freshly harvested, glutaraldehyde treated or cryogenically preserved. An anastomotic device application instrument, such as those described above, could also be supplied in the procedural kit with one of the anastomotic devices already attached to the distal end of the instrument. (Gifford; column 69, lines 45-62).

However, neither this cited text nor any other part of Gifford describes, expressly or inherently, the claimed functional package. Indeed, Gifford is completely silent as to the packaging of the anastomosis device or the tool for deploying the anastomosis device. Gifford alludes to a "kit," but fails to disclose any description of that kit whatsoever, much less provide an enabling disclosure under MPEP 2121. Thus, Gifford does not describe "a tray in which at least one recess is defined...wherein at least one said recess is configured to hold a biocompatible fluid."

Gifford neither expressly nor inherently describes each and every element claimed in claim 1, and Applicants believe claim 1 is in condition for allowance. Claims 2-15 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claims 2-5, the pull through tool is a mechanism that is movable relative to the anastomosis device to pull a graft vessel through the crown to a position in which it can be everted over the anastomosis device. (*e.g.*, Figures 5A, 7, 18; Specification, page 16, lines 1-15). However, the Office Action analogized the pull-through tool to the vessel punch 120 of Gifford. The vessel punch 120 includes an outer tube 131 that is moved relative to an anvil to enlarge a pre-existing opening in a target vessel. (*e.g.*,

Gifford, Figures 3, 5A-5B; column 16, lines 33-41; column 17, lines 3-31). The vessel punch 120 of Gifford has nothing to do with the graft vessel at all; it does not pull the graft vessel relative to the anastomosis device to facilitate its eversion over that anastomosis device. Further, the vessel punch 120 is not used to prepare a graft vessel for anastomosis, but rather is used during anastomosis to enlarge a pre-existing opening in the target vessel. Thus, the vessel punch 120 of Gifford is not analogous to the claimed pull-through tool, and Gifford does not disclose a pull-through tool; consequently, the rejection of claims 2-5 over Gifford should be withdrawn.

With regard to dependent claims 6-8 and 10, the poke through tool is a mechanism that is movable relative to the anastomosis device to cause the tines of the anastomosis device to poke through the graft vessel. (*e.g.*, Figures 16-17; Specification, page 21, line 5 through page 22, line 4). The poke-through tool is separate and distinct from the anastomosis device. However, the Office Action analogized the poke-through tool to a component of an anastomosis device: the fourth segment 111 of an attachment leg 105 of one part 101 of the two-part anastomosis device 100 of Gifford. (e.g., Gifford, Figure 1, column 13, lines 24-25 and 33-54; column 14, lines 18-30). Gifford does not describe a poke-through tool movable relative to the anastomosis device to cause the tines of the anastomosis device to poke through the graft vessel. Thus, the fourth segment 111 of Gifford is not analogous to the poke-through tool, and Gifford does not disclose a poke-through tool; consequently, the rejection of claims 6-8 and 10 over Gifford should be withdrawn.

Claims 41, 42, 44, 45

The Examiner objected to claim 43, but indicated that it would be allowable if rewritten in independent form. Independent claim 41 has been amended to include the

limitations of claim 43, which had previously depended from claim 41 and is now canceled. Thus, claim 41 is believed to be in condition for allowance.

Claims 42, 44 and 45 depend from claim 41, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 9-10

Claims 9-10 depend from claim 1, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claim 9 claims the "system of claim 1, further comprising an eversion shield held on said crown, said eversion shield covering said anastomosis device." In contrast, neither Gifford nor WO 01/91628 of Podmore ("Podmore") teach or suggest, alone or in combination, all of the limitations of claim 9. First, as stated above, Gifford does not teach or suggest all of the limitations of parent claim 1, the limitations of which are encompassed within the scope of its dependent claim 9. In addition, as the Office Action stated, Gifford does not disclose an eversion shield. Second, like Gifford, Podmore does not teach or suggest

anything in regard to the packaging of an anastomosis device or an applicator thereof, much less "a functional package comprising a tray in which at least one recess is defined...wherein at least one said recess is configured to hold a biocompatible fluid." For these first two reasons alone, the combination of Gifford and Podmore fails to teach or suggest all of the limitations of claim 9. Third, Podmore does not teach or suggest an eversion shield held on a crown, where that eversion shield covers an anastomosis device. Podmore discloses "tine shields" that are "moved (preferably by rotating them) into place, effectively hiding the tines of the [anastomosis] element." (Podmore, page 20, lines 14-16). The tine shields are part of an "installation apparatus" and are rotatably mounted to a carriage 11. (*e.g.*, Podmore, page 16, lines 25-32; Figures 8-12) The anastomosis device 20 is placed, by itself, on an anvil 25 of the installation apparatus, and the anastomosis device 20 is removed from the anvil 25 after the graft vessel has been attached to it. (e.g., Podmore, Figures 11-12, page 17, lines 2-4; page 17, line 20 through page 18, line 23; page 20, lines 7-11). Thus, Podmore neither teaches nor suggests a crown attached to or otherwise associated with the anastomosis device 20, and the tine shields of Podmore necessarily cannot be "held on [a] crown," as required by claim 9.

Further, there is no suggestion or motivation in Podmore to combine its teachings with those of Gifford. For example, Podmore discusses the disadvantages of an anastomosis device having a rigid ring such as that disclosed in Gifford. (Podmore, page 5, lines 32-35) Further, Podmore states that "the inside lining of the vessel walls (intima) should make contact with each other." (Podmore, page 5, lines 35-36) In contrast, Gifford discloses brining the inside lining of the graft vessel into contact with the outer surface of the target vessel. (Gifford, Figures 5F-5G). Consequently, there is no suggestion or motivation in Podmore to combine its teachings with Gifford.

The Office Action states that "Podmore teaches that an eversion shield is provided in order to protect the graft from premature puncturing by the tines of the anastomosis device." (Office Action, page 3). Applicants do not admit that Podmore teaches the use of an eversion shield for such a purpose, but point out that protection against "premature puncturing" is not claimed in claims 9 or 10.

Neither Gifford nor Podmore, alone or in combination, teach or suggest all of the limitations of claim 9, and Applicants believe claim 9 is in condition for allowance. Claim 10 depends from claim 9, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

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